SUMMIT
PATHOLOGY

Specimen Submission Guide

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Table of Contents

Gynecologic Cytology and Affiliated Molecular Testing

Specimens submitted to Summit Pathology must be labeled with two separate and unique identifiers, as required by the College of American Pathologists (CAP). All specimens must be accompanied by a Summit Pathology requisition form. If you are out of forms, please go to our website, www.summitpathology.com and go to the "Forms" tab. Print the requisition labeled "Cytology/Molecular/AP Requisition". Requisition forms must be completed with patient name, date of birth, complete address and phone number, insurance information, date of specimen collection, physician name, appropriate clinical history, ICD10 code, site of specimen, and testing requested. Specimen containers must be labeled with two separate and distinct identifiers and must be labeled on the container, not the lid. Specimen containers should be placed into the main part of the plastic biohazard bags supplied by Summit Pathology. The requisition form should be placed into the outer pouch of the bag.

Pap Tests

Summit Pathology accepts the following Papanicolaou modalities: ThinPrep® and conventional slide Pap tests. Please reference the attachments at the end of this guide for proper collection technique for the ThinPrep® liquid Pap test. Please remember that use of lubricants can interfere with adequate sampling of the ThinPrep® Pap test. An additional attachment at the end of this guide explains this further. Pap specimens do not need to be refrigerated.

Attachment 1 - ThinPrep® Specimen Collection Guide
Attachment 2 – Lubricant Use with the ThinPrep® Pap test

HPV

Summit Pathology uses the Roche COBAS HPV Test. This test for the Human Papillomavirus, which screens the following high risk sub-types: 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66 and 68. In addition to the screening result, this test will provide positive or negative results individually for the 16 and 18 genotpyes. The specimen sample for this test can be taken from the ThinPrep® Pap vial. Summit Pathology keeps pap specimens in our lab for six weeks. HPV tests can be added at any time in the six week window.

Chlamydia & Gonorrhea

Summit Pathology uses the Gen-Probe® Aptima® II Combo Assay for Chlamydia and Gonorrhea testing. The specimen sample for this test can be taken from the ThinPrep® Pap vial. Those tests can be added to a pap that was sent to Summit Pathology for one month after the specimen was received.

However, if you are not taking a liquid based pap specimen, **or** the patient is male, there are two other options. A urine specimen may be submitted using the Gen-Probe® Aptima Urine

Specimen Collection Kit. You may also submit a swab specimen using the Gen-Probe® Aptima Unisex Specimen Collection Kit for Endocervical and Male Urethral Swab Specimens. Both the urine and swab kits may be used for male and female patients. The Pap may only be used for female patients. Swab and urine kit specimens do not need to be refrigerated. Photos of these kits are included as Attachments 3 and 4.

Herpes

Summit Pathology sends requests for Herpes testing to Access Genetics, who report molecular detection of Herpes Simplex Virus, both Type 1 and Type 2. The specimen sample for this test can be taken from the ThinPrep® Pap vial. Those tests can be added to a pap that was sent to Summit Pathology for one month after the specimen was received.

If you are not taking a liquid based pap specimen, or the patient is male, the BD Universal Viral Transport may be used to obtain a swab specimen. A photo of this kit is included as Attachment 5. For best results, unroof the lesion before obtaining a specimen. This type of specimen does not need to be refrigerated.

Vaginosis Panel (Gardnerella, Trichomonas, Candida) Mycoplasma and Tier 2 Pathogens Testing

Summit Pathology utilizes two options to test for Gardnerella, Trichomonas and Candida: the BD Affirm™ VPIII Microbial Identification Test or from the ThinPrep pap vial. Instructions for submitting the Affirm™ VPIII Ambient Temperature Transport System can be found in Attachment 6. A photo of the Affirm VPIII Ambient Temperature Transport System is included in Attachment 7. This specimen must be tested within 72 hours of specimen collection.

If no BD Affirm™ VPIII kit is sent, a pathogens panel testing for Gardnerella, Trichomonas and Candida can be performed from the pap vial. Tier 2 testing is ONLY from the liquid pap vial. In Tier 2 testing, if the specimen is positive for Candida, a Candida Species profile is done. And if the specimen is negative for Gardnerella, a test for Atopobium vaginae is performed. In addition, testing for Mycoplasma can be performed on specimen from a liquid pap vial.

Non-Gynecologic Cytology

Specimens submitted to Summit Pathology must be labeled with two separate and unique identifiers, as required by the College of American Pathologists (CAP). All specimens must be accompanied by a Summit Pathology requisition form. If you are out of forms, please go to our website, www.summitpathology.com and go to the "Forms" tab. Print the requisition labeled "Cytology/Molecular/AP Requisition". Non-GYN cytology information is located on the bottom portion of the form. Requisition forms must be completed with patient name, date of birth, complete address and phone number, insurance information, date of specimen collection, physician name, appropriate clinical history, ICD10 code, site of specimen, and testing requested. When patients have a TB or Covid infection at the time of specimen submission, that history must be indicated on the requisition form. There are specific CDC guidelines for handling infectious specimens. Specimen containers must be labeled with two separate and distinct identifiers and must be labeled on the container, not the lid. Specimen containers should be placed into the main part of the plastic biohazard bags supplied by Summit Pathology. The requisition form should be placed into the outer pouch of the bag.

Body Fluids

Body fluid, such as ascites, peritoneal, thoracentesis pericardial, pleural and pericardal should be submitted fresh, when obtained at a facility with pathology services on site, and should be refrigerated until pickup by a Summit authorized courier. Please provide as much volume as possible, up to 1 liter. Be sure to include history of TB/ Covid and breast cancer if applicable.

Breast/ Nipple Discharge

Should be submitted on an alcohol fixed or air dried slide. Slides must be labeled with two distinct patient identifiers also included on the requisition (full name and DOB).

Brushes

Brushes, such as bronchial and ureteral should be fixed in CytoLyt to cover the specimen.

Washings (bronchial, bronchial alveolar lavage, whole lung lavage, pelvic or abdominal wash RUQ, LUQ,RLQ,LLQ)

Washigs should be submitted in CytoLyt, as much volume as possible. Be sure to include history of TB/Covid and breast cancer if applicable.

Cerebrospinal Fluid

Submit CSF 2 – 5ml unfixed. DO NOT send to Summit if there is a history or suspicion of Prion disease.

Fine Needle Aspiration

Fine needle aspirations from the breast, thyroid, lymph nodes, liver, pancreas, parotid, or gastric should be submitted in CytoLyt Solution. (Please see attachment 8 for the SOP procedure Non-pathologists Assisted FNA Thyroid). Volume should include at least 1 pass.

Include history of TB/Covid and breast cancer if applicable. Joint fluid should be sent in Cytolyt, as much as can be made available. If sending in a syringe, please remove the needle and send with a stop cap.

Sputum

Sputum should be submitted in CytoLyt Solution, at least 2ml preferred. Please include history of TB/Covid.

Urine

Urine (voided or catheterized, bladder, kidney, renal, ureter or urethral washes) should be submitted in 50% alcohol. Indicate which method was used to obtain the specimen (voided, catheter, bladder wash). Be sure to include requests for FISH testing if desired.

Anal Pap Smear

Send in PreservCyt (ThinPrep) vial. Keep in mind that additional molecular testing (such as HPV) cannot be performed on specimens sent in formalin.

Biopsies

Specimens submitted to Summit Pathology must be labeled with two separate and unique identifiers, as required by the College of American Pathologists (CAP). All specimens must be accompanied by a Summit Pathology requisition form. If you are out of forms, please go to our website, www.summitpathology.com and go to the "Forms" tab. Print the requisition labeled "Surgical Pathology Requisition". Requisition forms must be completed with patient name, date of birth, complete address and phone number, insurance information, date of specimen collection, physician name, appropriate clinical history, ICD10 code, site of specimen, and testing requested. Specimen containers must be labeled with two separate and distinct identifiers and must be labeled on the container, not the lid. Specimen containers should be placed into the main part of the plastic biohazard bags supplied by Summit Pathology. The requisition form should be placed into the outer pouch of the bag.

Specimens for routine pathological evaluation should be submitted in 10% neutral buffered formalin. The amount of formalin should ideally be at least 10 times the volume of the specimen. A formalin health hazard label must be on each container (OSHA requirement). Be certain that small specimens do not get caught in the lid or the side of the container. The in-formalin times should be documented on the requisition for known or suspected breast malignancies, since these specimens may be sent for ancillary testing, and should be attempted for all breast specimens, per CAP requirement. If the specimen is submitted in a fluid other than formalin, indicate which fluid is present (saline, etc.) All biopsies should be submitted in formalin with the exception of:

- Fresh or frozen section specimens
- Flow cytometry specimens
- Lymph node biopsies
- Muscle and nerve biopsies
- Renal biopsies
- Skin biopsies for immunofluorescence or electron microscopy
- Bone marrow biopsies for flow cytometry
- Specimens submitted for chromosome analysis
- Products of conception if cytogenetic analysis is requested
- Specimens submitted for evaluation of gout/ crystals

Fresh or Frozen Specimen Procedures

Specimens that are submitted fresh or for frozen section should only be taken from hospital or surgery center locations where a pathologist is available on call. Please follow the following procedure at the appropriate facility:

DURING BUSINEES HOURS (M-F 7:30AM – 5PM)

- Banner North Colorado Medical Center
  - **FIRST** call 970-810-4836 (pathology gross room at NCMC)
  - If no immediate answer, call Summit Pathology 970-212-0530

- McKee Medical Center
  - **FIRST** call 970-820-1379 (pathology gross room at McKee)
  - If no immediate answer, call 970-820-4133 (McKee Main Laboratory)
  - If no immediate answer, call Summit Pathology 970-212-0530

- Medical Center of the Rockies
  - **FIRST** call 970-624-2088 (MCR Gross Room)
  - If no immediate answer call pathologist on call 970-212-0530

- Poudre Valley Hospital
  - **FIRST** call 970-495-8743, option 1 (PVH gross room)
  - If no immediate answer call 970-495-8740 option 1 (PVH pathology)
  - If no immediate answer call pathologist on call 970-212-0530

- Cheyenne Regional Medical Center
  - **First** call 307-634-9238 (Summit Cheyenne main line)
  - If no immediate answer call 307-633-7065 (ASCOM)
  - If no immediate answer call pathologist on call 970-212-0530

- VA Hospital Cheyenne
  - **First** call 307-634-9238 (Summit Cheyenne main line)
  - If no immediate answer call 307-633-7065 (ASCOM)
  - If no immediate answer call pathologist on call 970-212-0530

- Ivinson Memorial Hospital
  - **First** call 307-755-4433 (Ivinson gross room)
  - If no immediate answer call 307-755-4440 (IMH main lab)
  - If no immediate answer call pathologist on call 970-212-0530

- UCH Greeley Hospital
  - **FIRST** call 970-652-2093 (GH Gross Room)
  - If no immediate answer call 970-652-2082 (Pathologist's office)

- If no immediate answer call pathologist on call 970-212-0530

- Banner Wyoming Medical Center Casper
  - **First** call all the gross room at 307-233-8134
  - If no immediate answer call the pathologist office at 307-233-8166
  - If no immediate answer call the pathologist on call at 970-212-0530

- Estes Park Medical Center
  - Call Summit Pathology at 970-212-0530 during business hours **ONLY** to schedule

- East Morgan County Hospital
  - Call Summit Pathology at 970-212-0530 during business hours **ONLY** to schedule

- Sterling Regional Medical Center
  - Call 970-521-3156 (SRMC pathology office) during business hours **ONLY** to schedule
- Banner Fort Collins Medical Center
  - Call Summit Pathology at 970-212-0530 during business hours **ONLY** to schedule

AFTER BUSINEES HOURS call the pathologist on call at 970-212-0530

Flow Cytometry Specimens

Flow cytometric studies require viable cells, therefore specimens should be submitted fresh, or in an appropriate fixative such as RPMI, not formalin. Please be a specific as possible in identifying the specific site of the biopsy, for example: "lymph node, left axilla". Appropriate clinical history should include CBC/ SPEP results, peripheral smear reviews, assessment for lymphadenopathy/ splenomegaly, 'B' symptoms, prior cytogenic studies, travel history, etc. The most common types of specimens submitted for flow include:

- Bone marrow aspirate, peripheral blood, lymph node biopsy material and body fluids such as pleural or cerebrospinal fluid.
- If lymphoma/ hematopoietic malignancy is a clinical possibility, the specimen should be submitted fresh.
- Bone marrow aspirate material and peripheral blood may be placed in green or purple top tubes. Please submit at room temperature, do not refrigerate. Please notify the lab if additional studies are requested (e.g. cytogenetics, specific markers to assess for myeloproliferative disease, FISH)
- Solid tissue, such as lymph nodes and body fluids may be submitted in sterile containers.

Lymph Node Biopsies

If lymphoma/ hematopoietic malignancy is a clinical possibility, submit the tissue fresh (without formalin) for possible flow cytometric studies. Lymph nodes submitted for disease process other than lymphoma/ leukemia (e.g. metastatic carcinoma) should be placed in a formalin container. Please be as specific as possible when identifying the specimen collection site and include appropriate clinical history, including CBC/ SPEP results, peripheral smear reviews, assessment for lymphadenopathy/ splenomegaly, 'B' symptoms, prior cytogenic studies, travel history, etc.

Muscle and Nerve Biopsies

Skeletomuscular pathology and peripheral nerve studies (for weakness) require special studies and expertise in these areas. Summit Pathology refers these cases to the University of Colorado for processing and assessment. Muscle biopsies should be 15 mm long with a diameter of 5-10 mm. Sutures around the width of the specimen help to orient it correctly.

Two (2) 20 mm long specimens should be submitted for nerve biopsies.

Both muscle and nerve biopsies should be wrapped in moist saline gauze. Do not float the specimen in saline.

Specimens should be delivered the day of the procedure, so advanced notice of a procedure is critical.

Renal Biopsies

Renal pathology is a highly specialized area, requiring several special techniques for full evaluation. Summit Pathology does not process renal biopsies for medical disease evaluation in our laboratory. We do process and evaluate biopsies for renal masses and tumors, however. Currently, Summit Pathology refers all medical renal biopsies to a reference laboratory for evaluation. Here are several general guidelines for these specimens:

- Proper evaluation of renal biopsies for medical disease requires evaluation of tissue under light microscopy, electron microscopy, and immunofluorescent histology. Each of these requires proper fixation of the biopsy material.
- Usually, the tissue is divided at the time of the procedure for proper preservation. The portion for light microscopy is placed in 10% formalin. The portion for electron microscopy is placed in 1% glutaraldehyde (Trumps fixative). The portion for immunofluorescent histology is placed in Zeus tissue fixative. All of these fluids are available as part of the Mayo Clinic Renal Biopsy kit, stocked by all our affiliated hospital laboratories.
- You will also need to complete the Renal Biopsy Patient Information Sheet. As these biopsies are sent to Mayo by our affiliated laboratories, please contact the appropriate hospital laboratory to arrange transport.

Skin Biopsies for Immunofluorescece

Currently, Summit Pathology forwards skin specimens to a reference laboratory for immunofluorescence studies. Specimens should be submitted in Zeus (also called Michel's) fixative or saline. These tubes are available from Summit Pathology. There is also a separate requisition form to be filled out for immunofluorescence studies. A separate specimen should also be submitted, in the same bag, for histologic studies done at Summit Pathology. Both specimen containers can be submitted in the same bag to Summit Pathology.

Bone Marrow Biopsies

Please notify your hospital laboratory when a specimen is ready for submission. General guidelines for bone marrow biopsies are:

- Bone marrow cores are placed in formalin.
- A portion of the bone marrow aspirate should be placed two green top tubes and one purple top tube for possible flow cytometry and cytogenetic studies. Any remaining aspirate should be placed in formalin for 'clot sections'. Bone marrow particles for the aspirate smears are obtained from the green top tube.
- Unstained smears are made for cytochemical studies, when indicated (acute leukemia).
- **A CBC and peripheral smear should be ordered and performed within 24 hours of the procedure.**
- Please be specific with site of specimen. For example, if you want the report to state that the specimen was a posterior iliac crest biopsy rather vertebral biopsy, please let us know. Include appropriate clinical history, such as CBC results, electrophoresis, etc.
- **Please notify the hospital laboratory when the specimen is ready, as these biopsies require urgent handling.**

Chromosome Analysis Not From Placenta

Chromosome analysis is most commonly performed on lymphoid material or bone marrow aspirate material/ peripheral blood. Lymphoid material should be submitted in RPMI. Peripheral blood and/or bone marrow aspirate should be submitted in a sodium heparin (green top) tube. These studies are performed at a reference laboratory.

Products of Conception

The procedure and handling of products of conception varies between hospital systems that are served by Summit Pathology. Please call your local clinical laboratory to determine the proper procedure.

Placentas

Placentas should be sent for pathology in formalin, just enough to cover the specimen. If chromosome studies are requested, DO NOT send the specimen in formalin, send fresh. Placentas should be submitted in a sealed plastic specimen container, NOT directly in a biohazard bag. The container should then be placed in a biohazard bag.

Gout/ Crystal Specimens

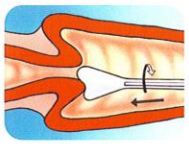
If a specimen is requested to be evaluated for gout or crystals, it must be submitted fresh (without fluid or chemical). Indicate on the requisition form that gout is suspected so the specimen will be handled appropriately.

Attachment 1

ThinPrep® Specimen Collection Guide

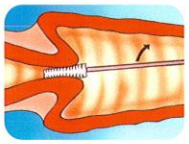
Quick Reference Guide
Endocervical Brush/Spatula Protocol

THE ThinPrep® PAP TEST



Obtain...
an adequate sampling from the ectocervix using a plastic spatula. If desired, use lukewarm water to warm and lubricate the speculum. Water-soluble gel lubricant sparingly applied to the posterior blade of the speculum can be used if necessary.[1] Select contoured end of plastic spatula and rotate it 360 degrees around the entire exocervix while maintaining tight contact with exocervical surface.

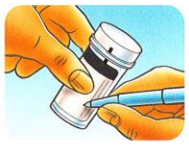
Rinse...
the spatula as quickly as possible into the PreservCyt® Solution vial by swirling the spatula vigorously in the vial 10 times. Discard the spatula.



Obtain...
an adequate sampling from the endocervix using an endocervical brush device. Insert the brush into the cervix until only the bottom-most fibers are exposed. Slowly rotate 1/4 or 1/2 turn in one direction. DO NOT OVER-ROTATE.

Rinse...
the brush as quickly as possible in the PreservCyt Solution by rotating the device in the solution 10 times while pushing against the PreservCyt vial wall. Swirl the brush vigorously to further release material. Discard the brush.

Tighten...
the cap so that the torque line on the cap passes the torque line on the vial.



Record...
the patient's name and ID number on the vial.

Record...
the patient information and medical history on the cytology requisition form.

Place...
the vial and requisition in a specimen bag for transport to the laboratory.

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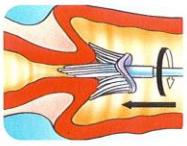
SIDE 1 OF 2

Quick Reference Guide
Broom-Like Device Protocol

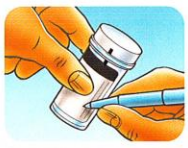
THE ThinPrep® PAP TEST



Obtain...
an adequate sampling from the cervix using a broom-like device. If desired, use lukewarm water to warm and lubricate the speculum. Water-soluble gel lubricant sparingly applied to the posterior blade of the speculum can be used if necessary.[1] Insert the central bristles of the broom into the endocervical canal deep enough to allow the shorter bristles to fully contact the ectocervix. Push gently, and rotate the broom in a clockwise direction five times.

Rinse...
the broom as quickly as possible into the PreservCyt® Solution vial by pushing the broom into the bottom of the vial 10 times, forcing the bristles apart. As a final step, swirl the broom vigorously to further release material. Discard the collection device.

Tighten...
the cap so that the torque line on the cap passes the torque line on the vial.



Record...
the patient's name and ID number on the vial.

Record...
the patient information and medical history on the cytology requisition form.

Place...
the vial and requisition in a specimen bag for transport to the laboratory.

www.thinprep.com

1. Cervicovaginal Cytology Based on the Papanicolaou Technique; Approved Guideline – Third Edition (Clinical and Laboratory Standards Institute GP15-A3).

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Attachment 2

Lubricant use with the ThinPrep® Pap test

January 30, 2012

Re: Lubricant use during Pap sample collection

Dear Colleague,

On occasion, Hologic personnel are asked to provide information concerning the use of lubricants when collecting a Pap sample using the ThinPrep® Pap Test. As part of Hologic's continuing education for clinicians and laboratorians, this bulletin addresses the proper preparation of the cervix for an adequate Pap sample collection pertaining to the ThinPrep Pap Test and the use of lubricants on the speculum. Steps taken by the clinician, from patient education to improved sampling technique, may ensure that the sample collected maximizes the potential of the Pap test.[1,2]

Patient Education:

Women should be counseled to refrain from intercourse, douching, using tampons, or using intravaginal medication for at least 48 hours before the examination to decrease the possibility that the number of exfoliated cells will be diminished or obscured by personal lubricants or spermicides.[1,2] In addition, the patient should avoid scheduling her appointment during heavy menstrual bleeding.[1] If you would like Hologic patient education materials for your office, please visit www.hologiccustomersolutions.com.

Sample Collection Options for Lubricating the Speculum:

1. **Lukewarm Water:** For a patient without physical or physiologic reasons for needing lubricant, lukewarm water may be used to warm and lubricate the speculum. This protocol has the least risk to the quality of the Pap sample collected. [1,3] Professional organizations including ACOG and CLSI recognize that excessive use of lubricant may contaminate or obscure the Pap sample.

2. **Lubricant Gels:** If lubricant must be used due to patient discomfort or other circumstances, lubricant should be used sparingly and applied ***only*** to the exterior sides of the speculum blades, ***avoiding contact with the tip of the speculum***.[1,2,3,4] (see pictures below) When a lubricant is used sparingly and appropriately, it poses little risk to the quality of the Pap sample. However, when a lubricant is used in excess, it can adversely affect the Pap sample. Hologic evaluated a variety of popular lubricants and found those containing carbomer or carbopol polymers (thickening agents) interfere with the ThinPrep Pap test when found in the sample vial.[5] Hologic recognizes the varying availability of different types of lubricants and recommends that, if used, any lubricant should be applied sparingly as described below.

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Appropriate Use of Lubricant for Pap Collection

Lubricant gels should be used sparingly.	Apply only to exterior sides of the speculum, avoiding the tip.
	

Should you have further questions regarding this topic, please refer to the CLSI guidelines or contact Hologic Technical Support Department at 1-800-442-9892, option 6.

Sincerely,

Edward Evantash
Medical Director

1. Davey *et al*, 2008, "Cervical Cytology Specimen Adequacy: Patient Management Guidelines and Optimizing Specimen Collection"; American Society for Colposcopy and Cervical Pathology Journal of Lower Genital Tract Disease, Volume 12, Number 2, 2008, 71-81
2. Amies, AE.; Miller, L; Lee, Shu-Kuang; Koutsky, L, The Effect of Vaginal Speculum Lubrication on the Rate of Unsatisfactory Cervical Cytology Diagnosis, Obstet Gynecol. 100(5, Part 1):889-892, November 2002.
3. "Cervicovaginal Cytology Based on the Papanicolaou Technique; Approved Guideline – Third Edition", Clinical and Laboratory Standards Institute (formerly NCCLS), Vol. 28 No. 28, 2008.
4. ACOG Practice Bulletin, Clinical Management Guidelines for Obstetrician Gynecologists, Number 109, December 2009, pg 2.
5. Hologic internal study, Data on file.

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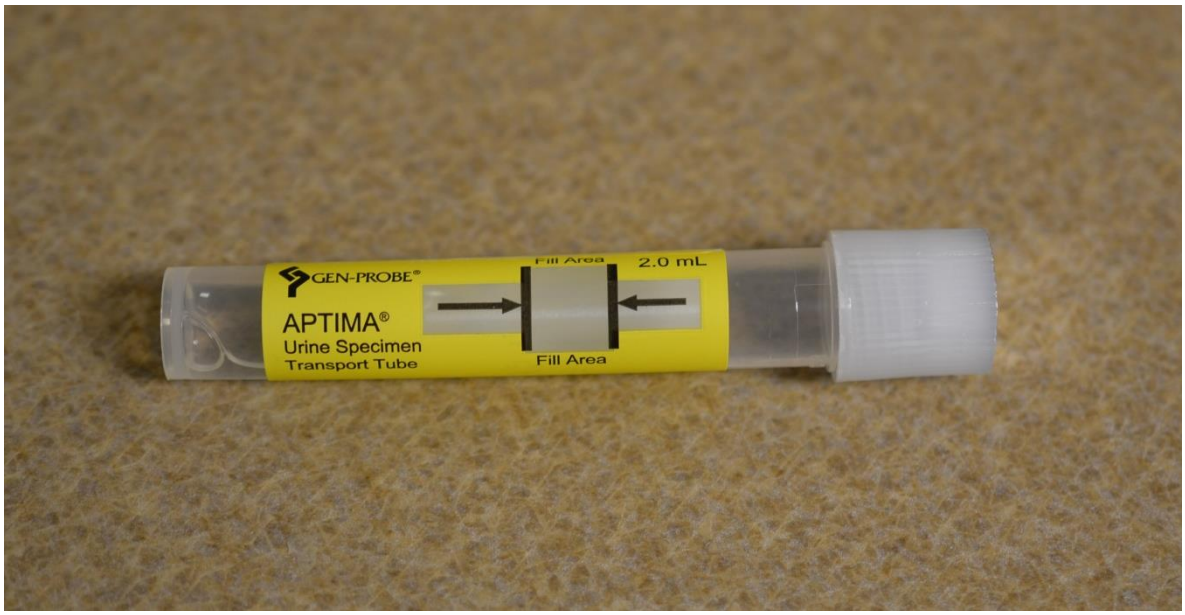
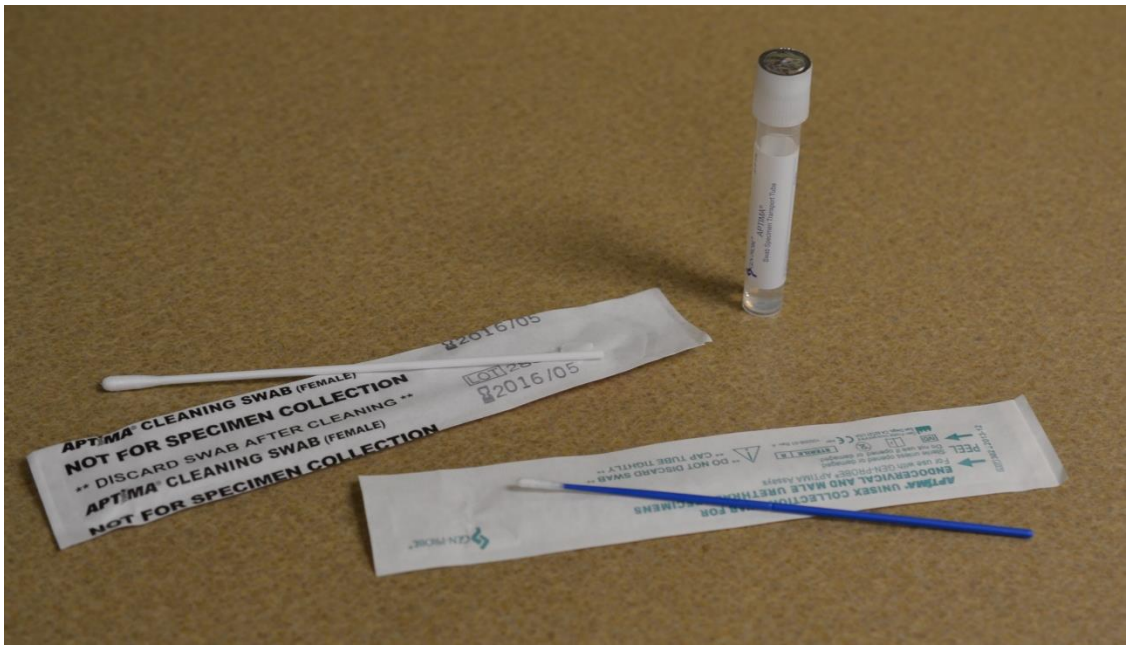
Attachment 3

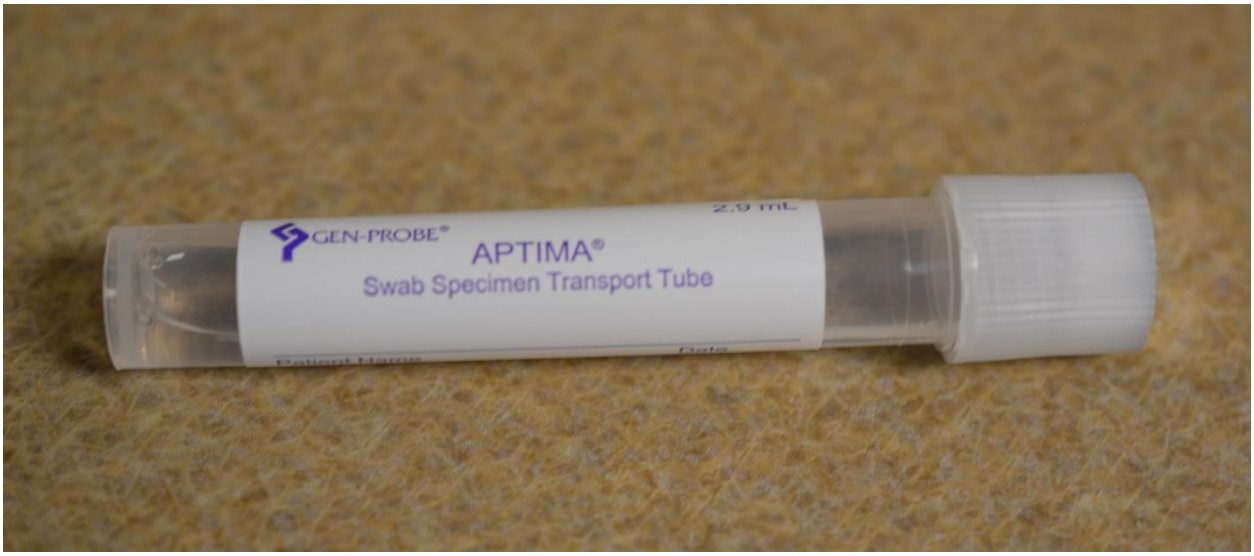
Gen-Probe® Aptima Urine Specimen Collection Kit


GEN-PROBE®
APTIMA®
Urine Specimen
Transport Tube
Fill Area
2.0 mL
Fill Area

Attachment 4

Gen-Probe® Aptima Unisex Swab Specimen Collection Kit


APTIMA CLEANING SWAB (FEMALE)
NOT FOR SPECIMEN COLLECTION
** DISCARD SWAB AFTER CLEANING **
APTIMA CLEANING SWAB (FEMALE)
NOT FOR SPECIMEN COLLECTION
2016/05
2016/05


GEN-PROBE
APTIMA
Swab Specimen Transport Tube
2.9 mL

Attachment 5

BD Universal Viral Transport System


BD
Universal Viral
Transport
Sterile Swab
Applicators

Attachment 6

BD Affirm™ VPIII Microbial Identification Test Collection Guide
(Vaginosis Panel: Gardnerella, Trichomonas, Candida)

BD Affirm™ VPIII Collection and Transport

BD Affirm™ VPIII Ambient Temperature Collection System

For collection of vaginal specimens for use in the BD Affirm™ VPIII Microbial Identification Test for *Candida, Gardnerella* and *Trichomonas*. See reverse side for transport procedures.

VAGINAL SAMPLE COLLECTION

Sample collection is a critical step. Personnel collecting vaginal fluid specimens should be well trained to ensure adequate sample collection. **All samples must be collected using the materials (swabs and tubes) provided in the set.**

1. Place the patient in position for a pelvic examination. Insert a speculum into the vagina to permit visualization of the posterior vaginal fornix.
2. Using the sterile swab, obtain a sample from the posterior vaginal fornix. Twist or roll the swab against the vaginal wall two or three times, ensuring the entire circumference of the swab has touched the vaginal wall. Swab the lateral vaginal wall while removing the swab. (see Figure 1)
3. Immediately place the swab in the Sample Collection Tube (SCT).
4. With the swab touching the **BOTTOM** of the collection tube, grasp the pre-scored handle of the swab just above the top of the tube and bend until the swab breaks (Figure 2). When the swab is fully inserted into the collection tube, the score mark on the swab is approximately 1 cm above the top of the collection tube. Discard the broken handle into an infectious waste container.
5. Place the cap over the exposed end of the swab and firmly press the cap onto the tube. The cap will "snap" onto the tube when it is properly seated.
6. Label the **Sample Collection Tube (SCT)** with the patient identification information. Include the time the sample was collected.
7. Place the capped **Sample Collection Tube (SCT)** into the plastic **Sample Transport Bag** for transport for testing with the **Affirm** VPIII Microbial Identification Test.

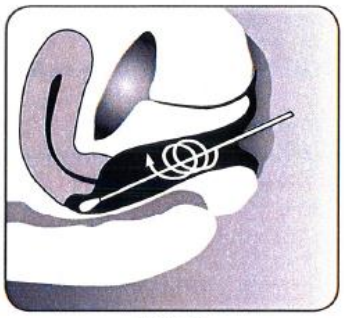


Figure 1

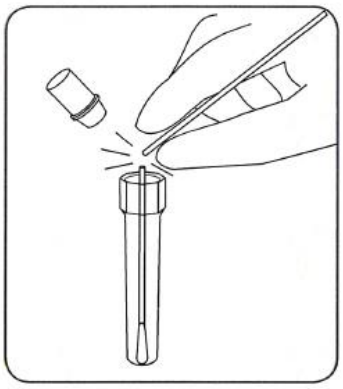


Figure 2

BD

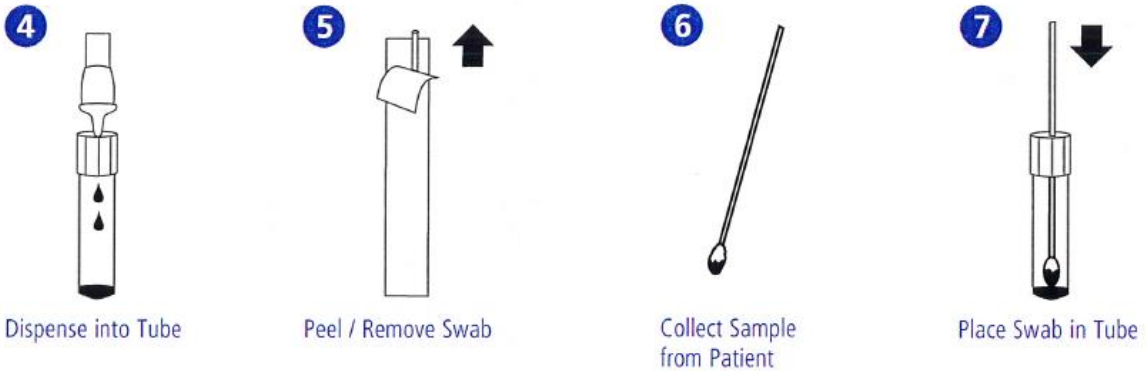
Helping all people live healthy lives

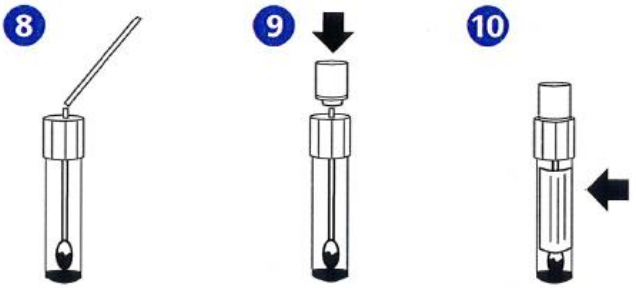
BD Affirm™ VPIII Collection and Transport

BD Affirm™ VPIII Ambient Temperature Transport System

For transport of vaginal specimens for use in the BD Affirm™ VPIII Microbial Identification Test for *Candida, Gardnerella* and *Trichomonas*. See reverse side for collection procedures.

TRANSPORT





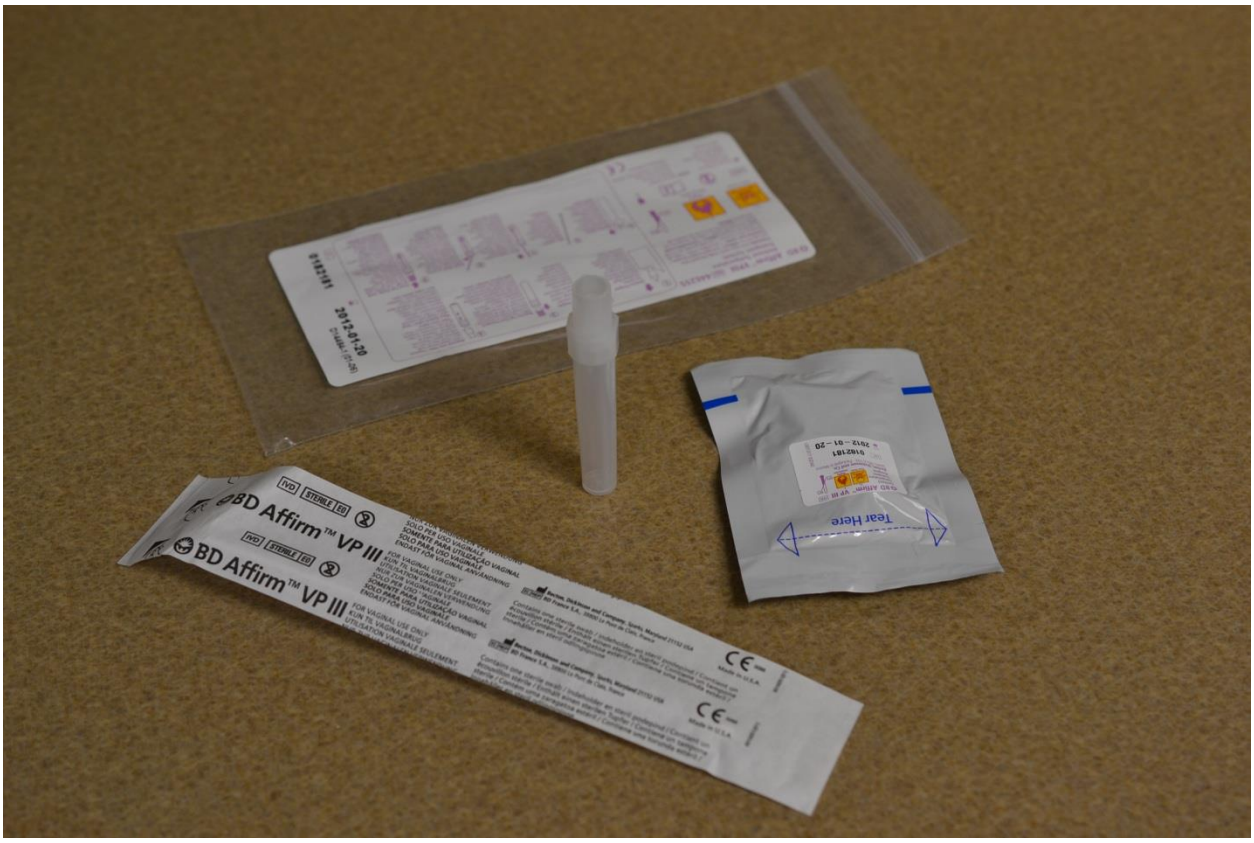
Sample is stable for 72 hours at ambient temperature (15-30°C) or refrigerated (2-8°C) storage.

BD

BD Diagnostics
7 Loveton Circle
Sparks, MD 21152-0999
800.638.8663
www.bd.com/ds

Attachment 7

BD Affirm™ VPIII Ambient Temperature Transport System


BD Affirm™ VP III
BD Affirm™ VP III
Tear Here

Attachment 8

Non-Pathologist Assisted FNA SOP

Facilities: *Summit Pathology*	**PROCEDURE**	**Document #:** LS0301

NON-PATHOLOGIST ASSISTED FINE NEEDLE ASPIRATION COLLECTION

SUMMIT PATHOLOGY

PURPOSE:

This document provides instructions for radiologist, primary care providers, radiology technicians, nurses and other health/laboratory assistants in the collection and preparation of fine needle aspirations at facilities without a staffed pathologist.

PRINCIPLE:

Upon request of the radiologist and/or primary care provider, an assistant and or technician, will attend the fine needle aspiration collection, prepare the smear and properly label and package the specimen for transport to Summit Pathology. This procedure is not pathologist assisted so adequacy and rapid interpretation will not be given at the time of procedure.

SUPPLIES:

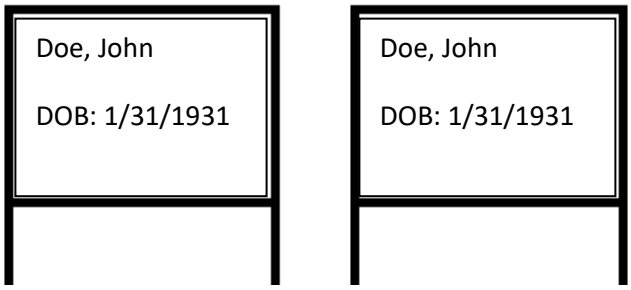
The following supplies should be kept in the collection suite or on a moveable cart to be transported to the FNA collection suite.

1. CytoLyt container (3 of 30 ml. vials)
2. Afirma® vial
3. Coplin jar containing 95%
4. Empty slide container
5. Clean glass slides

6. Sterile slides (if requested by performing physician)
7. Syringes
8. 4X4 gauze
9. Gloves (all sizes)
10. Xylene proof pen/pencil
11. Extra requisitions
12. Cold Pack (to chill Afirma® vial)
13. 10% formalin vials (12 of 20 ml. vials) if tissue is to be taken for histology

Fine Needle Aspiration Collection

1. Verify with attending nurse that the patient is the same as noted on the requisition.
2. Arrange clean slides in preparation for making smears.
   A. If needle is to be re-used per performing physician request, open sterile slide package and arrange slide with frosted label side up on sterile packaging insert (creating a small "sterile field").
3. Label each slide on the frosted side, with full patient name (first and last), the patient's birthdate, pass number (ie, A1, A2….), and site letter. The slides must contain two full patient identifiers. Repeat this step for 3 sets of slides (6 total slides), one set for each biopsy pass.



   A. Note: 2-3 passes are standard in order to prepare adequate slide smears. An additional 2 passes are to be collected for Afirma (see below) for a total of 4-5 passes.
4. Verify that the patient requisition and labels are available (proper labeling will be needed for all vials and requisitions).
   A. The tech/assistant must note on the requisition:
      1. That the specimen is for "Cytology."
      2. Each site location and corresponding letter designation
      3. Performing physician and requesting physician name
      4. Date of Service
      5. Any relevant history for the pathologist:
         a. ie. size of nodule and it's laterality. ie. cystic/solid. ie. hx of papillary ca.
5. Once the sample is collected, the radiologist performing the procedure will hand the needle, with or without an accompanying syringe, to the tech/assistant.
   A. If the needle is not attached to a syringe, attach a syringe to the needle and expel the fluid onto a glass slide.

6. After collected material is placed onto one slide, smear evenly with a second slide labeled for that pass.
7. Slides are then placed into coplin jars.
   A. One slide immediately placed into coplin jar containing 95% alcohol.
   B. The second identically labeled slide placed into slide container labeled “AIR DRIED”.
   C. Repeat steps A-B for each pass aspirated onto slides.
8. Provide a clean CytoLyt vial for expression of the needle for contents to be submitted for cytology. If the needle is to be reused, do not insert needle into the CytoLyt fluid.
   A. Label this vial with a patient ID sticker as well as appropriate collection site.
   B. If multiple sites are sampled, provide a separate CytoLyt vial for each and label with patient ID sticker as well as appropriate site.

Thyroid FNA Collection for Afirma® Gene Expression Classifier Test

1. Following collection for cytology, two additional passes from each site are collected for potential send out for Afirma® testing.
2. Affix a hospital patient identification label to the Afirma® FNAprotect™ Collection Tube.
   A. Fold the label around the tube and seal adhesive ends, then wrap label around tube to allow placement into the Afirma® Sample Storage Box.
3. Place the needle tip of the aspiration syringe into the Afirma® vial fluid and aspirate a small amount of fluid into the syringe. Place the needle tip against the inside of the vial above the fluid level and gently express the contents into the vial.
   A. Repeat this step to rinse any remaining specimen contents into the vial.
4. Invert the tube three times to mix material properly.
5. If there are aspirates representing more than one site, label each Afirma® Collection Tube accordingly.
6. Place all slide containers, properly labeled CytoLyt vials and Afirma® tubes accompanying requisition, and cold pack into a biohazard bag and prepare for courier transport to Summit Pathology Laboratory according to site protocol.
7. Call Summit Pathology for more FNA kits, or with any other questions you may have.
   - Phone: 970-212-0530
   - Fax: 970-212-0553

Additional Collection Notation:

1. Any collection that is not “routine” (ie. placed in CytoLyt or Afirma® tube) must be clearly documented on the requisition. Be specific, for example:
   A. “Sample placed into saline for thyroglobulin testing”.

B. “Sample placed into RPMI for flow cytometry”.
C. “Cores obtained and placed into formalin.”
D. TB
E. Covid
F. Breast CA